

PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Standing Committee on Health, Aged Care and Sport

**Approval processes for new drugs and novel medical technologies in
Australia**

3 September 2020

PDR Number: IQ20-000624

Number of drugs awaiting approval in Australia

Spoken

Hansard Page number: 6

Senator: Milton Dick

Question:

Mr DICK: I've got just one question. How many drugs are waiting for approval at the moment in Australia?

Dr Cook: I'm sorry, I don't know that off the top of my head.

CHAIR: For TGA?

Mr DICK: Yes.

CHAIR: For which an application has been lodged?

Mr DICK: Yes.

Dr Skerritt: We can take that on notice—

Dr Cook: We can take that on notice, but I don't have that off the top of my head.

Dr Skerritt: yes—because of course there are new drugs and also generic drugs, and there'll be many more generic drugs and there are variations.

Answer:

As at 3 September 2020, there were 49 new chemical entity applications, 57 extension of indications applications, 5 new combination medicine applications and 95 new generic medicine applications for TGA registration.

In addition, there were 1046 active applications to vary existing prescription medicines (for example, changes to dose, strength, route of administration or safety information).